

### REMARKS

The Office Action of February 10, 2006, has been received and reviewed. Claims 1-4, 6 and 8-45 are currently pending in the application. Claims 11-26 and 31-44 are withdrawn from consideration as being directed to a non-elected invention. Claims 11, 13, 14, 24, 31, 34, 38, 40, 41, 44, and 45 have been cancelled herein. Claims 1-4, 6, 8-10, 27-30 and 45 stand rejected. Claims 1 and 27 are amended herein. All amendments and cancellations are made without prejudice or disclaimer. Reconsideration is respectfully requested. This response is filed within six (6) months of the mailing date of the Office Action (February 10, 2006). Submitted herewith is a Petition for Extension of Time under 37 C.F.R. § 1.136(a) for a two (2) month extension and a Request for Continued Examination.

#### Rejections Under 35 U.S.C. § 112, 1st Paragraph

Claims 1-4, 6, 8-10, 27-30 and 45 stand rejected under 35 U.S.C. § 112, first paragraph, for assertedly failing to comply with the written description requirement. Claim 45 has been canceled, thus the rejection is moot as to this claim. Applicants respectfully traverse the rejection. Reconsideration and withdrawal of the written description rejections are respectfully requested.

Although the applicants do not agree that the application does not comply with the written description requirement, to expedite prosecution, claims 1 and 27 have been amended herein. Claims 1 and 27 now recite “providing said yeast cell with a nucleic acid encoding said ectodomain or functional part thereof selected from the group consisting of parts spanning from amino acid residue 25-442, 97-318, 97-442, and 97-545” and “providing a yeast cell with an isolated or recombinant “nucleic acid encoding *Plasmodium falciparum* AMA-1 ectodomain or a functional part thereof selected from the group consisting of parts spanning from amino acid residue 25-442, 97-318, 97-442, and 97-545,” respectively.

An applicant may show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that the applicant was in possession of the claimed invention, *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. *Enzo*

*Biochem v. Gen-Probe Inc.*, 323 F.3d 956, 964, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002); *see also* MPEP §§ 2161-2163.

Applicants respectfully assert that the claims 1 and 27, as amended, comply with the written description requirement. Applicants provide both complete and partial structures, to wit: “wherein the encoding nucleic acid consists of a sequence as depicted in FIG. 1, or wherein the encoding nucleic acid consists of a sequence that comprises at least 90 percent homology to the corresponding sequence as depicted in FIG. 1.” Further, applicants provide distinct physical and chemical properties, to wit: “wherein said *Plasmodium falciparum* AMA-1 ectodomain exhibits specificity for mAb 4G2.” As such, applicants respectfully submit that claims 1 and 27 fulfill the written description requirement. Further, applicants assert that claims 2-4, 6, 8-10, and 28-30 are allowable at least as depending, directly or indirectly, from independent claims 1 and 27. As such, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

#### **Rejection Under 35 U.S.C. § 102(b)**

Claims 1-3, 5-6, 9-10, 27-30 and 45 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Kocken *et al.* Claim 45 has been canceled, thus the rejection is moot as to this claim. Claim 5 was previously canceled. Applicants respectfully traverse the rejection.

As noted by the Examiner on Page 10 of the instant Office Action, “Kocken *et al.* teach the expression of *P. vivax* AMA-1.” By way of contrast, independent claims 1 and 27 recite *Plasmodium falciparum*. Further, the “functional part” of *Plasmodium falciparum* has been amended to recite a functional part thereof “selected from the group consisting of parts spanning from amino acid residue 25-442, 97-318, 97-442, and 97-545.” Support for the amendment may be found throughout the as-filed specification including, for example, paragraph [0012] and paragraphs [0055]-[0062]. As Kocken *et al.* does not teach each and every element of independent claims 1 and 27, to wit, expression of the *P. falciparum* AMA-1 ectodomain or a functional part thereof selected from the group consisting of parts spanning from amino acid residue 25-442, 97-318, 97-442, and 97-545, applicants respectfully assert that Kocken *et al.* cannot anticipate the claims 1 and 27.

Furthermore, applicants respectfully assert that claims 2-3, 6, 9-10, and 28-30 are allowable at least as depending, directly or indirectly, from independent claims 1 and 27. As such, reconsideration and withdrawal of the rejection of claims 1-3, 6, 9-10, and 27-30 under 35 U.S.C. § 102(b) are respectfully requested.

**Rejection Under 35 U.S.C. § 103(a)**

Claims 1-3, 5-6, 9-10, 27-30 and 45 stand rejected under 35 U.S.C. § 103(a) as assertedly being obvious over Kocken *et al.* in view of Withers-Martinez. Claim 45 has been canceled, thus the rejection is moot as to this claim. Claim 5 was previously canceled. Applicants respectfully traverse the rejection.

As stated herein, Kocken fails to teach or suggest expression of the *P falciparum* AMA-1 ectodomain or a functional part thereof selected from the group consisting of parts spanning from amino acid residue 25-442, 97-318, 97-442, and 97-545 as recited in independent claims 1 and 27. Kocken also fails to teach or suggest “wherein at least one glycosylation site is removed from said *Plasmodium falciparum* AMA-1 ectodomain.” Withers-Martinez fails to cure the deficiencies of Kocken. Further, the proposed combination fails to teach or suggest that once at least one glycosylation site has been removed, such proteins would still fold like native proteins.

Additionally, no motivation exists to combine the two references. Independent claims 1 and 27 require that the *Plasmodium falciparum* AMA-1 ectodomain exhibit specificity for mAb 4G2. In other words, the natural conformation of the AMA-1 ectodomain is required. In Withers-Martinez, the protein that is collected from *P. pastoris* is not in its natural conformation as very harsh methods need to be used to obtain the protein from the cells. (See, e.g., Withers-Martinez page 1115, middle of left column, “[t]here days following induction, 20 g of cells were lysed using a cell disrupter and resuspended in a denaturing buffer.”) The authors also state that “[o]ur preliminary expression results are extremely encouraging; PfSUB-1 is expressed intracellularly in *P. pastoris* in the range of 0.2-0.5 g/L, providing enough material for extensive **refolding** assays.” (Withers-Martinez, page 1119, right hand column end of first paragraph)(emphasis added). Thus, Withers-Martinez teaches that no native material is produced but rather the material needs to be refolded.

On the other hand, parallel experiments were performed by the same authors in insect cells. (Withers-Martinez, paragraph bridging columns on page 1115). Protein folding occurs correctly in the insect cells as the protein was detected in the culture supernatant. (*Id.*, last sentence of paragraph). Thus, Withers-Martinez teaches away from production of native *P. falciparum* proteins in *P. pastoris* and in fact teaches that insect cells are better suited for this purpose. Thus, one skilled in the art would be motivated by Kocken in view of Withers-Martinez to use insect cells which is not the presently claimed invention.

As the combination of Kocken in view of Withers-Martinez fails to teach or suggest every element of the presently claimed invention, applicants respectfully submit independent claims 1 and 27 are not rendered obvious by the proposed combination of art. Reconsideration and withdrawal of the rejection is requested.

Furthermore, applicants respectfully assert that claims 2-3, 6, 9-10, and 28-30 are allowable at least as depending, directly or indirectly, from independent claims 1 and 27. As such, reconsideration and withdrawal of the rejection of claims 1-3, 6, 9-10, and 27-30 under 35 U.S.C. § 103(a) are respectfully requested.

**CONCLUSION**

In view of the foregoing, applicants respectfully request removal of the rejections and kindly ask reconsideration of the claims. Claims 1-4, 6, 8-10, and 27-30 are believed to be in condition for allowance and an early notice thereof is kindly requested. If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' agent at the address or telephone number given herein.

Respectfully submitted,



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